UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	**ORAL ARGUMENT REQUESTED**

ZHP DEFENDANTS' REPLY IN SUPPORT OF MOTION TO SEAL

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STATUTE

The ZHP Defendants seek to seal very limited portions of a report submitted by their organic chemistry expert that include highly technical information about ZHP's manufacturing and testing processes. Plaintiffs' assertion that the ZHP Defendants have not established good cause to keep this information from public view is based on misrepresentations of the facts. For one thing, Plaintiffs vastly overstate the breadth and content of the material the ZHP Defendants seek to seal, which is limited to chemistry information underlying ZHP's processes that is valuable only to ZHP and its competitors. Plaintiffs also inaccurately assert that Jucai Ge – whom Plaintiffs have deposed on two occasions in connection with this litigation, including once as ZHP's corporate representative on valsartan-related issues – somehow lacks personal knowledge regarding valsartan because she recently took a new position at a subsidiary of ZHP.

Plaintiffs' argument that there is a countervailing public interest in disclosure of chemistry-related information because absent class members need it to decide whether to opt out of the litigation is similarly baseless. The information about ZHP's testing processes that the ZHP Defendants seek to redact consists primarily of chemical information and formulas, which have nothing to do with product safety or the merits of Plaintiffs' claims. Thus, such information would not be useful to – or likely even understood by – anyone other than ZHP and its competitors. As a result, the ZHP Defendants' motion to seal should be granted.

ARGUMENT

I. PLAINTIFFS CANNOT REFUTE THAT THE ZHP DEFENDANTS HAVE ESTABLISHED GOOD CAUSE TO REDACT THE CONFIDENTIAL INFORMATION ABOUT THE SPECIFICS OF ZHP'S MANUFACTURING PROCESSES.

As set forth in the ZHP Defendants' opening brief, the limited portions of the expert report of Fengtian Xue, Ph.D. ("Xue Report") proposed for redaction contain sensitive, confidential, proprietary and highly technical information related to ZHP's manufacturing and testing processes, as well as how and why those processes changed over time, that could be easily adapted and used by competitors to the detriment of the ZHP. (Mem. at 10-11.) Plaintiffs' arguments in response misrepresent both: (1) the type of information proposed for redaction and bases for the confidentiality claims; and (2) the role of Jucai Ge at ZHP and in this litigation.

A. The Proposed Redactions At Issue Include Undisclosed Information About ZHP's Manufacturing And Testing Processes That Would Give Competitors A Business Advantage.

Plaintiffs advance a number of arguments as to why the limited information proposed for redaction should not be sealed, but all of these arguments are based on mischaracterizations of the facts and law at issue.

First, Plaintiffs' assertion that the ZHP Defendants seek "to seal significant portions of [their] primary liability expert's report" (Pls.' Opp'n at 1) is factually baseless. Defendants submitted reports from ***nine*** experts in connection with the

liability phase of litigation, of whom Dr. Xue – an organic chemist – is only one.[1] Notably, the ZHP Defendants do not seek to seal any of the portions of Dr. Xue's report that contain his affirmative opinions or respond substantively to Plaintiffs' experts' reports. Instead, they seek to redact specific, technical details regarding ZHP's manufacturing and testing processes for, and molecular makeup of, ZHP's valsartan active pharmaceutical ingredient ("API"). These targeted redactions appear on just 13 pages of Dr. Xue's 58-page report. (*See* Cox Cert. at 3 (Mem. Ex. 2).) Further, a review of the proposed redactions makes clear that the overwhelming majority of the information the ZHP Defendants seek to seal simply lists the specific chemicals, the quantities of those chemicals, temperatures, and techniques that the ZHP Defendants used ***and continue to use*** in their processes to manufacture valsartan API. (*See generally* Xue Rep.)[2] Other redactions cover conclusions made by ZHP regarding the specific technical benefits of certain changes in manufacturing processes. (*See, e.g.*, *id*. at 26-27.) As explained in the ZHP Defendants' opening brief (*see* Mem. at 11-13) and in Section II below, this highly technical information would be of little use to anyone other than the ZHP

[1] Notably, Dr. Xue was not the only organic chemist presented by the Defendants. (*See generally* ECF No. 2333 (opposing Plaintiffs' motion to exclude defense expert and organic chemist Steven W. Baertschi, Ph.D.).)

[2] A version of the Xue Report with the ZHP Defendants' proposed redactions was submitted to the Court via email on July 20, 2023.

and its competitors, which is why courts in this District have held that such information is subject to confidentiality protection. *See, e.g., Supernus Pharms., Inc. v. TWi Pharms., Inc.*, No. 1:15-cv-00369-RMB-JS, 2019 WL 13043557, at *2 (D.N.J. June 17, 2019) ("The confidential information at issue here—the specific formulation of Twi's ANDA products—has extremely limited public utility. This information is useful only to those businesses that would seek to benefit, to Twi's detriment, in the highly competitive generic pharmaceutical marketplace.").

Second, there is also no merit to Plaintiffs' argument that the information proposed for redaction is already available to the public. Plaintiffs assert that the information at issue is included in the publicly-available patents for ZHP's valsartan API and that the patents provide adequate protection from competitive harm if the information were made publicly available. (Pls.' Opp'n at 13-14.) But the patents do not include the same level of technical detail regarding ZHP's manufacturing processes and testing protocols as the portions of the Xue Report proposed for redaction. For example, the 2014 patent cited by Plaintiffs merely notes that the tetrazole-formation step of the valsartan manufacturing process should occur at a temperature between 80 and 135° C and for a duration of 8 and 35 hours. (Pls.' Opp'n, Ex. 2 at 2.) Similarly, the 2018 patent notes a new "temperature range of the tetrazolium ring-forming reaction . . . [of] 70-180° C" and a "preferred reaction temperature range [of] 100-140° C." (Pls.' Opp'n, Ex. 3

at 2.) By contrast, the Xue Report provides the specific temperature and duration of ZHP's tetrazole-formation step. (Xue Rep. at 27.) Because ZHP's competitors could use these specific details, which are not included in the valsartan API patents, to improve their own manufacturing processes, this information is entitled to protection. *See Immunomedics, Inc. v. Roger Williams Med. Ctr.*, No. 15-4526 (JLL) (SCM), 2016 WL 10572644, at *1-2 (D.N.J. Dec. 22, 2016) (cited in Mem. at 9, 11) (sealing materials on the basis that "the [p]arties will suffer injury and/or competitive harm"); *Joint Stock Soc'y v. UDV N. Am., Inc.*, 104 F. Supp. 2d 390, 409 (D. Del. 2000) ("*UDVNA*") (noting that because "there has been no public disclosure of the defendants' old vodka recipes," the defendants were entitled to maintain documents containing those recipes under seal).

In addition, the mere existence of ZHP's patents does not prevent ZHP's competitors from using confidential information about manufacturing and testing processes for valsartan API to their competitive advantage. For one thing, the valsartan API patents provide no protection for the various details of the ZHP Defendants' testing for impurities, including impurities other than nitrosamines, that are included in the Xue Report. (*See, e.g.*, Xue Rep. at 34-36.) In addition, the patents protecting ZHP's manufacturing processes, the latest of which was filed in July 2018 (Pls.' Opp'n, Ex. 3 at 1), are only valid in the United States for 20 years from the date they were filed. *See* 35 U.S.C. § 154. As a result, ZHP can

only ensure protection of the specific details of its manufacturing and testing processes moving forward by maintaining their confidentiality. *See, e.g., Pike v. Tex. EMC Mgmt., LLC*, 579 S.W.3d 390, 409 (Tex. App. 2017), *order withdrawn* (Apr. 12, 2019), *rev'd on other grounds*, 610 S.W.3d 763 (Tex. 2020) (concluding that specific material omitted from a patent application was protected as a trade secret).

Plaintiffs' argument that portions of Dr. Xue's report that describe the "structures of . . . chemicals are public knowledge and easily found on Google" is similarly baseless. (Pls.' Opp'n at 14.) The ZHP Defendants assume that Plaintiffs are referring to the redaction of several charts included in the Xue Report that detail the chemical structures of potential non-nitrosamine impurities in valsartan API. (*See* Xue Report at 34-36.) But it is not the chemical structure of these potential impurities that is confidential; rather, it is the "details regarding ZHP's testing for impurities, including whether the evaluations were affected by the process changes and, if so, how." (*See* Decl. of Jucai Ge ("Ge Decl.") ¶ 10 (Mem. Ex. 3).) The disclosure of this non-public information would reveal "technical knowledge that ZHP has gained through expense and effort" (*id.*), which would be "useful only to those businesses that would seek to benefit, to [ZHP's] detriment, in the highly competitive generic pharmaceutical marketplace," *Supernus Pharms., Inc.*, 2019 WL 13043557, at *2.

Third, Plaintiffs inaccurately assert that the portions of the Xue report that the ZHP Defendants seek to seal are not confidential because they are not copied directly from ZHP's Drug Master File ("DMF") for valsartan. (Pls.' Opp'n at 1.) As explained in the ZHP Defendants' opening brief and supporting materials, the information the ZHP Defendants seek to protect is substantially similar, if not identical, to the information contained in a DMF and is widely recognized within the industry as being highly confidential. (*See, e.g.*, Mem. at 7-9.) Indeed, the "FDA is ***specifically prohibited*** from disclosing . . . all data or information submitted with or incorporated by reference" in ANDAs, including the substantive information included in DMFs. *In re Gabapentin Pat. Litig.*, 312 F. Supp. 2d 653, 660 (D.N.J. 2004) (citation omitted). Further, as explained in the opening brief, courts routinely grant motions to seal materials other than a DMF where, as here, they contain non-public information regarding "proprietary manufacturing processes" used by a party. *See Immunomedics, Inc.*, 2016 WL 10572644, at *1, *2; *Supernus Pharms., Inc.*, 2019 WL 13043557, at *2. Plaintiffs fail to address – much less distinguish – these on-point authorities.

Fourth, Plaintiffs' argument that information related to ZHP manufacturing processes that are no longer in use is not confidential (*see* Pls.' Opp'n at 15) misunderstands both the ZHP Defendants' bases for sealing and the relevant caselaw. For one thing, the information the ZHP Defendants seek to redact, even if

technically related to past manufacturing processes, would provide competitors with insight regarding the manufacturing and testing processes that are currently in use. (Ge Decl. ¶¶ 6, 9.) Moreover, Plaintiffs are unable to point to any caselaw suggesting that confidential information regarding a company's manufacturing and testing processes is only entitled to protection from disclosure if those processes are currently in use – and at least one district court in this Circuit has held to the contrary. *See UDVNA*, 104 F. Supp. 2d at 409 (rejecting argument that "formulas ha[d] lost their trade secret value," and should not be sealed, where "they [were] not currently used by the defendants" because the information had "the potential to confer independent economic value" to competitors if disclosed). Similarly, here, technical information about ZHP's past manufacturing and testing processes – which at the very least informs processes in use today – would be valuable to competitors, and its public disclosure would therefore put ZHP at a competitive disadvantage. (*See* Mem. at 10-11; Ge Decl. ¶¶ 6, 9.)

Fifth, Plaintiffs' contention that this Court – and others in this District – have rejected motions to seal in similar circumstances is based on a misreading of the caselaw. For example, Plaintiffs rely on *Centennial Mill by Del Webb Community Association v. Ply Gem Holdings, Inc.*, in which the court rejected a motion to seal based on the argument that disclosure of the information at issue would subject a party to potential future litigation and/or harm the party's legal

arguments. No. 1:17-cv-7675 (NLH/JS), 2018 WL 3085210, at *5 (D.N.J. June 22, 2018) (denying request to seal based on the assertion that "[p]ublic access to information concerning the alleged 'thermal distortion' in settlement communications and negotiation could disadvantage [d]efendants ***in other matters/litigations***") (emphasis added). But the ZHP Defendants do not contend that the confidential information at issue is relevant to the substance of any legal claims in connection with the current or other litigation. To the contrary, the limited portions of the Xue report that the ZHP Defendants seek to seal contain highly technical scientific information that is only valuable to ZHP and its competitors.

Plaintiffs' reliance on some of this Court's prior rulings rejecting confidentiality claims is similarly misplaced. In *In re Valsartan N-Nitrosodimethylamine (NDMA), Losartan, & Irbesartan Products Liability Litigation*, for example, the Court sustained Plaintiffs' challenge to another defendant's designation of five email chains as confidential based on a finding that the materials did not "have the potential 'for causing [significant] competitive harm to [the defendant] or giving a competitive advantage to others" because "[a]t bottom, [the defendant's] emails [at issue] involve[d] what appear[ed] to be routine business communications." 512 F. Supp. 3d 546, 554 (D.N.J. 2021). Further, the Court specifically found that the "emails [did] not contain any references, nor [did]

[the defendant] cite to, a proprietary procedure or practice" and that "none of the emails list[ed] or reference[ed] proprietary formulas or ingredients other than general references that are likely accessible in documents prepared by or filed with the FDA." *Id.* By contrast here, the information at issue exclusively includes ***propriety procedures, practices, formulas and ingredients*** that are not publicly available. (*See* Ge Decl. ¶¶ 5-10.) Moreover, Ms. Ge has specifically explained that the release of the information at issue "would result in significant commercial harm to ZHP by revealing to its competitors detailed information regarding its manufacturing processes, including its current manufacturing processes." (*Id.* ¶¶ 3, 6.)

Nor does *In re Avandia Marketing, Sales Practices & Products Liability Litigation*, 484 F. Supp. 3d 249 (E.D. Pa. 2020) ("*Avandia II*") support Plaintiffs' position. There, GSK sought to redact more than 55 documents that pertained directly to the substance of the plaintiffs' allegations that the company failed to adequately warn about the increased risk of physical injury caused by the diabetes drug Avandia, "including clinical studies, GSK submissions to the FDA, internal GSK emails and letters, records of teleconferences between GSK and the FDA, Avandia presentations and plans, and some court filings in the MDL." (Pls.' Opp'n at 6-7 (quoting *Avandia II*, 484 F. Supp. 3d at 264-65).) But GSK did not identify any ***competitive*** injury that would result from disclosure – and instead

argued that it would subject the company to liability under European Union privacy laws. *Avandia II*, 484 F. Supp. 3d at 265. The court rejected that argument as to all but a limited set of redactions based on a finding that "GSK would not [in fact] be subject to penalties under EU law" if the materials were disclosed. *Id.* at 266. In addition, GSK sought to seal the entirety of certain of plaintiffs' experts' reports on grounds that they contained "inaccurate, incomplete, and biased representations . . . about the safety and efficacy of Avandia" that would "jeopardize the health of current Avandia patients by eroding their trust in their doctors' prescribing decisions." *Id.* at 262 (citation omitted). The court also rejected this argument because the same information about the safety of Avandia had been in the public sphere for more than a decade and was well known to doctors and patients. *Id.* at 264.

Here, by contrast, the ZHP Defendants have presented a declaration from ZHP's corporate representative explaining that the information at issue is highly confidential and would cause competitive harm to ZHP if disclosed. (*See* Ge Decl. ¶¶ 5-11.) As courts have recognized, this is a sufficient basis to grant a motion to seal. *See Immunomedics, Inc.*, 2016 WL 10572644, at *1; *Supernus Pharms., Inc.*, 2019 WL 13043557, at *2; *Everest Nat'l Ins. Co. v. Sutton*, No. 07-722 (JAP), 2010 WL 4387522, at *3, *6-7 (D.N.J. Oct. 28, 2010) (litigants entitled to prevent competitors from "unfairly us[ing] . . . otherwise confidential and proprietary

business information to their competitive advantage").

B. The Declaration Of Jucai Ge Provides Strong Evidentiary Support For The ZHP Defendants' Motion To Seal.

Plaintiffs' attacks on the validity of Ms. Ge's declaration – and its ability to support the ZHP Defendants' motion to seal – are also baseless. Ms. Ge is a longtime ZHP employee who has served as ZHP's corporate representative in connection with this litigation and been deposed repeatedly by Plaintiffs. Plaintiffs nonetheless argue that Ms. Ge's Declaration "runs afoul of Local Rule 5.3(c)(3), this Court's explicit prior guidance, and the related case law" (Pls.' Opp'n at 2) because she recently took a new job with a ZHP subsidiary and therefore purportedly no longer has personal knowledge related to valsartan. This argument is borderline frivolous.

Plaintiffs are unable to cite any cases holding or suggesting that only a current employee of a company may provide a declaration to support confidentiality claims. Rather, in both cases on which Plaintiffs rely, courts rejected motions to seal premised on declarations from ***outside counsel*** who admittedly lacked personal knowledge of the harms that would result from disclosure of the materials at issue. *See In re Caterpillar Inc., C13 & C15 Engine Prods. Liab. Litig.*, No. 14-3722 (JBS/JS), 2015 WL 12830520, at *3 (D.N.J. Jan. 29, 2015) (disregarding outside counsel's certification where counsel did "not attest to the fact that he ha[d] personal knowledge of the facts"); *Schatz-Bernstein*

v. Keystone Food Prod., Inc, No. CIV.08-3079-RMB-JS, 2009 WL 1044946, at *2-3 (D.N.J. Apr. 17, 2009) (similar). Here, by contrast, Ms. Ge has specifically declared, under penalty of perjury, that she has personal knowledge of the technical information about ZHP's manufacturing and testing processes that the company seeks to redact and the competitive harms that would result if it were revealed to competitors. (Ge Decl. ¶ 1.) And Plaintiffs' counsel are well aware that the declaration is accurate, having deposed Ms. Ge about the personal knowledge she gained working for ZHP for more than two decades, including as the Director of ZHP's Quality Assurance department, while ZHP was using both the manufacturing and testing processes at issue in this litigation and the processes that are currently in use. (*See, e.g.*, 4/27/21 Ge Dep. 17:20-21 (attached as Ex. 1 to the Certification of Jessica Davidson ("Davidson Cert.")); *id*. 64:6-9; *id*. 25:4-6; 5/27/22 Ge Dep. 238:19-22 (Davidson Cert. Ex. 2).) As a result, Plaintiffs' assertion that Ms. Ge lacks personal knowledge of the relevant facts because the ZHP subsidiary for which she currently works is headquartered in a different province of China and "does not appear in any defendant's production" (Pls.' Opp'n at 1-2) is disingenuous.

For all of these reasons, the ZHP Defendants have established that specific competitive harms are likely to occur if the information at issue is publicly disclosed.

II. PLAINTIFFS HAVE NOT IDENTIFIED ANY LEGITIMATE PUBLIC INTEREST IN THE DISCLOSURE OF THE INFORMATION AT ISSUE THAT OUTWEIGHS ZHP'S INTEREST IN ITS CONTINUED CONFIDENTIALITY.

Plaintiffs also cannot refute that there is no legitimate public interest favoring the disclosure of the technical manufacturing information at issue.

Plaintiffs argue that the proposed redactions to the Xue Report will somehow "prevent absent class members from assessing the merits of this case in deciding whether to opt out or commit themselves to the outcome of this Court's proceedings." (Pls.' Opp'n at 12.) But as explained above and in the ZHP Defendants' opening brief, none of the technical information the ZHP Defendants seek to seal relates to the safety of the product or goes directly to the merit of Plaintiffs' allegations. (*See generally* Ge Decl. ¶¶ 3, 7-10.)

To the extent class members seek to evaluate the merit of Plaintiffs' allegations in deciding to opt out of class membership, they have the benefit of Plaintiffs' pleadings, the parties' briefing at the motion-to-dismiss and class-certification stages, and the opinions of more than 15 experts for both Plaintiffs and Defendants, including the substantive opinions of Dr. Xue, which the ZHP Defendants do not seek to seal. By contrast, they have no need for the confidential, technical, chemistry-related information at issue here.

CONCLUSION

For all of the reasons set forth above, and those set forth in the ZHP Defendants' opening memorandum, the ZHP defendants respectfully request that the Court grant their Motion to Seal.

Dated: September 20, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on September 20, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ *Jessica Davidson*
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